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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,702	12/04/2003	Steve T. Cho	6711.US.C1	8659

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EXAMINER	
CORRIGAN, JAIME W	

ART UNIT	PAPER NUMBER
3748	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,702	CHO ET AL.	
	Examiner	Art Unit	
	Jaime W Corrigan	3748	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 33-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,33-40 and 42-45* is/are rejected.

7)☒ Claim(s) *41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-4-2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Sipin (PN 6,280,408).

Regarding claim 1 Sipin discloses a fluid line (See Figure 2 (46), (48); Column 7 Lines 1-4) through which the medicinal fluid is conveyed from the reservoir to a patient (See Column 1 Lines 8-13); a flow controller (See Figure 1 (16); Column 5 Lines 43-67, Column 6 Lines 1-8) that selectively varies a rate of flow of the medicinal fluid through the fluid line (See Column 1 Lines 1-13); a processor that is controllably coupled to the flow controller (See Figure 2; Column 7 Lines 17-25), said processor operating the flow controller so as to vary a rate at which the medicinal fluid flows through the fluid line (See Column 1 Lines 1-13); and a flow sensor that monitors a rate of flow of the medicinal fluid through the fluid line (See Figure 2 (36); Column 7 Lines 11-14), producing an output signal indicative thereof, said output signal being coupled to the processor, said processor controlling the flow controller in a closed-loop process as a

function of the signal, to achieve the desired rate of infusion of the medicinal fluid into a patient (See Column 2 Lines 35-40).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by DeVale (PN 5,464,391).

Regarding claim 33 DeVale discloses an orifice (See Figure 6 (92)) disposed in a fluid path (See Figure 5 (64)) through which a medicinal fluid flows in a fluid line, said orifice having a cross-sectional size that is substantially less (See Figure 6 (92)) than that of the fluid line; and a pressure-sensing module (See Figure 6 (54), Column 5 Lines 46-63) configured to sense a pressure drop across the orifice, said pressure sensor producing a signal in response thereto (See Figure 6 (54), Column 5 Lines 46-63).

Regarding claim 34 DeVale discloses the pressure sensing module further comprises a distal pressure sensor (See Figure 2 (52)) and a proximal pressure sensor (See Figure 2 (54)), said distal pressure sensor monitoring a distal pressure of the medicinal fluid, downstream of the orifice, and said proximal pressure sensor monitoring a proximal pressure of the medicinal fluid, upstream of the orifice, a difference between

the distal pressure and the proximal pressure determining the signal supplied to the processor, which is indicative of the rate of flow (See Abstract, Column 2 Lines 19-22) of medicinal fluid through the fluid line.

Regarding claim 35 DeVale discloses the pressure sensing module comprises a differential pressure sensor that monitors a differential pressure (See Figure 6 (54), Column 5 Lines 46-63) across the orifice and in response thereto, produces the signal supplied to the processor (See Figure 1 (20)), which is indicative of the rate of flow (See Abstract, Column 2 Lines 19-22) of medicinal fluid through the fluid line.

Regarding claim 36 DeVale discloses the flow sensor is disposable and is connected to the fluid line (See Figure 7 (52)).

Regarding claim 37 DeVale discloses a bypass channel (See Figure 11 (23)) within the fluid line, generally in parallel with the orifice, said bypass channel being selectively opened to enable the medicinal fluid to substantially bypass the orifice when a substantially greater rate of flow of the medicinal fluid than the desired rate is required through the fluid line (See Column 3 Lines 5-24).

Claims 38-40, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Rapoport et al. (PN 5,803,066).

Regarding claim 38 Rapoport discloses a flow sensor (See Figure 18 (72)) adapted to be disposed in a fluid path of a medicinal fluid flowing through a fluid line, said flow sensor producing a signal indicative of a rate (See Column 13 Lines 12-18) of flow of a medicinal fluid through the fluid path, said flow sensor includes an orifice disposed in the fluid path, said orifice (See Figure 18 (74)) having a cross-sectional size that is substantially less than that of the fluid path, both proximal and distal to the orifice, and a pressure-sensing module (See Figure 18 (90)) configured to sense a pressure drop across the orifice, said pressure sensor producing the signal (See Column 13 Lines 19-30) in response thereto.

Regarding claim 39 Rapoport discloses the pressure sensing module comprises a differential pressure sensor (See Figure 18 (90)) that monitors a differential pressure across the orifice and in response thereto, produces the signal supplied to the processor, which is indicative of the rate of flow (See Column 15 Lines 17-20) of medicinal fluid through the fluid line.

Regarding claim 40 Rapoport discloses the flow sensor (See Figure 18 (72)) is disposable and is coupled into the fluid path.

Regarding claim 42 Rapoport discloses a bypass channel (See Figure 7 (16)) within the fluid line, generally in parallel with the orifice, said bypass channel being selectively opened to enable the fluid to substantially bypass the orifice when a

substantially greater rate of flow of the fluid than the desired rate is required through the fluid line (See Column 5 Lines 24-28).

Claims 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Ortiz (PN 5,886,267).

Regarding claim 43 Ortiz discloses a body defining a first fluid flow passage (See Figure 1 (10)) having an inlet and an outlet, a flow restricting element (See Figure 1 (12)) located along the first fluid flow passage between the inlet and the outlet, an upstream fluid pressure sensor (See Figure 1 (14)) to sense an upstream fluid pressure at an upstream location in the first fluid flow passage between the inlet and the flow restricting element (See Figure 1 (12)), a downstream fluid pressure sensor (See Figure 1 (18)) to sense a downstream fluid pressure at a downstream location in the first fluid flow passage between the flow restricting element and the outlet, an upstream signal contact (See Figure 1 (20)) connected to the upstream fluid pressure sensor, and a downstream signal contact (See Figure 1 (24)) connected to the downstream fluid pressure sensor, and directing a fluid flow through the first fluid flow passage (See Column 3 Lines 56-62); obtaining a signal (See Figure 1 (40), (42), (45), (44), Column 4 Lines 56-67) corresponding to the fluid pressure in the first fluid flow passage at the locations of the upstream fluid pressure sensor and the downstream fluid pressure sensor; and determining a flow characteristic (See Column 2 Lines 48-51, Column 3 Lines 14-15) based upon the signal.

Regarding claim 44 Ortiz discloses determining the pressure difference between the upstream and downstream fluid pressure sensors (See Column 4 Lines 64-67, Column 5 Lines 1-39).

Regarding claim 45 Ortiz discloses the determining step further includes calculating flow rate of fluid through the first fluid flow passage based on the pressure difference (See Column 3 Lines 2-5).

Allowable Subject Matter

Claim 41 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Montalvo et al. (PN 5,489,265), Adams et al. (PN 6,539,315) disclose similar fluid flow devices.

Any inquiry concerning this communication from the examiner should be directed to Examiner Jaime Corrigan whose telephone number is (703) 308-2639. The examiner can normally be reached on Monday - Friday from 8:30 a.m. – 6:00 p.m. 2nd Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas E. Denion, can be reached on (703) 308-2623. The fax number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0861.

JC

Jaime Corrigan
Jaime Corrigan
Patent Examiner

March 31, 2004

Art Unit 3748

THOMAS DENION
SUPERVISORY PATENT EXAMINER
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